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Docket No.: F2842 US S3 (C018016/0180304)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Re Application of: )

Michael BARDROFF *et al.* )

Serial No.: 10/505,313 )

Filed: August 20, 2004 )

For: **ANTI-AMYLOID BETA ANTIBODIES  
AND THEIR USE**

Examiner: G. S. Emch

Art Unit: 1649

New York, New York  
October 14, 2009

**REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT**  
**UNDER 37 CFR § 1.705(b)**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

This Request For Reconsideration Of Patent Term Adjustment Under 37 CFR § 1.705(b) ("Request") is being filed in response to the Notice of Allowance and Fee(s) Due ("Notice") and Notice of Allowability mailed August 21, 2009. The Determination of Patent Term Adjustment Under 35 U.S.C. § 154(b) mailed with those papers indicates that the adjustment is only for **95 days**. We respectfully request reconsideration of this Determination.

The instant patent application was filed under 35 U.S.C. 371 on August 20, 2004. The Patent Term Adjustment History, as displayed on the PAIR system, is attached hereto as Exhibit A. Applicants do not address herein the Office's calculation

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of patent term adjustment under 35 U.S.C. § 154(b)(1)(A).<sup>1</sup> Applicants, however, respectfully request reconsideration of the Office's calculations of the patent term adjustment under 35 U.S.C. § 154(b)(2)(C). Specifically, Applicants respectfully request that the **198** day delay related to the submission of a response to a non-final Office Action (received in the Office on January 16, 2009) (the "January 16, 2009 Response") be reconsidered and reduced to **2** days. Thus, Applicants respectfully submit that the patent term adjustment is at least **291** days – a difference of **196** days from the Office's assessment of **95** days.

This Request is being filed before payment of the issue fee and is therefore timely. 37 CFR § 1.705(b).

We enclose a check for \$200.00 to cover the applicable fee. 37 CFR §§ 1.705(b)(1) and 1.18(e). Please charge any required fees not otherwise paid by check to Deposit Account No. 02-4467. A copy of this sheet is enclosed.

### **Facts of the Case**

The facts of the case are listed below, with the portions most relevant to this Request for Reconsideration underlined.

- The application entered U.S. national stage on August 20, 2004.

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<sup>1</sup> We note that because the application has not issued, patent term adjustment under 35 U.S.C. § 154(b)(1)(B) cannot be calculated as of this time. Indeed, the Patent Term History displayed on the PAIR system does not show a calculation under 35 U.S.C. § 154(b)(1)(B). Furthermore, on September 14, 2009, Mr. Mark Polutta of the Office of Legal Administration at the USPTO confirmed that patent term adjustment under 35 U.S.C. § 154(b)(1)(B) will be calculated only after the patent issues. Accordingly, Applicants do not raise issues related to or under 35 U.S.C. § 154(b)(1)(B) at this time but reserve the right to do so after issuance.

of patent term adjustment under 35 U.S.C. § 154(b)(1)(A).<sup>1</sup> Applicants, however, respectfully request reconsideration of the Office's calculations of the patent term adjustment under 35 U.S.C. § 154(b)(2)(C). Specifically, Applicants respectfully request that the **198** day delay related to the submission of a response to a non-final Office Action (received in the Office on January 16, 2009) (the "January 16, 2009 Response") be reconsidered and reduced to **2** days. Thus, Applicants respectfully submit that the patent term adjustment is at least **291** days – a difference of **196** days from the Office's assessment of **95** days.

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<sup>1</sup> We note that because the application has not issued, patent term adjustment under 35 U.S.C. § 154(b)(1)(B) cannot be calculated as of this time. Indeed, the Patent Term History displayed on the PAIR system does not show a calculation under 35 U.S.C. § 154(b)(1)(B). Furthermore, on September 14, 2009, Mr. Mark Polutta of the Office of Legal Administration at the USPTO confirmed that patent term adjustment under 35 U.S.C. § 154(b)(1)(B) will be calculated only after the patent issues. Accordingly, Applicants do not raise issues related to or under 35 U.S.C. § 154(b)(1)(B) at this time but reserve the right to do so after issuance.

- The application fulfilled the requirements of 35 U.S.C. § 371 on March 7, 2005.
- A Requirement for Restriction/Election was mailed on June 5, 2007.
- A response to the Requirement for Restriction/Election was received by the Office on July 27, 2007.
- A First Supplemental IDS was received by the Office on August 6, 2007.
- An Office Communication was mailed on October 18, 2007.
- A Response to the October 18, 2007 Office Communication was received by the Office on October 25, 2007.
- A Second Supplemental IDS was received by the Office on November 13, 2007.
- A non-final Rejection was mailed on January 28, 2008 (the "January 28, 2008 Office Action"). Exhibit B attached hereto is a copy of the January 28, 2008 Office Action.
- A Response to January 28, 2008 Office Action with a properly executed certificate of mailing and a two-month extension of time was timely mailed on June 30, 2008. The PTO received the Response on July 2, 2008 (the "July 2, 2008 Response"). Exhibit C attached hereto is a copy of the main text of the July 2, 2008 Response (without the Exhibit attached thereto) along with a date-stamped postcard evidencing such receipt.

- An Examiner Interview was conducted on July 9, 2008. An Interview Summary recording the substance of that Interview was mailed on July 28, 2008 (the "July 28, 2008 Interview Summary"). Exhibit D attached hereto is a copy of the July 28, 2008 Interview Summary.
- A Supplemental Response to the Office Action with a properly executed certificate of mailing and a three-month extension of time was timely mailed on July 24, 2008 in response to the January 28, 2008 Office Action. The PTO received the Response on July 28, 2008 (the "July 28, 2008 Supplemental Response"). Exhibit E attached hereto is a copy of the July 28, 2008 Supplemental Response along with a date-stamped postcard evidencing such receipt.
- An Office Communication was mailed on October 14, 2008 (the "October 14, 2008 Office Action"). Exhibit F attached hereto is a copy of the October 14, 2008 Office Action.
- A Response to the October 14, 2008 Office Action with a properly executed certificate of mailing and a two-month extension of time was timely mailed on January 13, 2009. The PTO received the Response on January 16, 2009 (the "January 16, 2009 Response"). Exhibit G attached hereto is a copy of the January 16, 2009 Response along with a date-stamped postcard evidencing such receipt.
- A Third Supplemental IDS was received by the Office on January 21, 2008.

- A Final Office Action was mailed on April 29, 2009. Exhibit H attached hereto is a copy of the Final Office Action.
- A response to the April 29, 2009 Final Office Action was received by the Office on July 31, 2009.

### **Review of Patent Term Adjustment Calculation**

The Office treated the July 2, 2008 Response as a submission of a reply having an omission (See Patent Term Adjustment History, "07-02-2008 Informal or Non-Responsive amendment after Examiner Action"). Furthermore, the January 16, 2009 Response was treated as a paper correcting a reply having an omission. Thus, according to the Office, the period of delay was from July 3, 2008 to January 16, 2009, or 198 days (37 CFR § 1.704(c)(7)). Indeed, the Patent Term Adjustment History shows a 198 day delay associated with the January 16, 2009 Response.

At issue is whether the claims submitted in the July 2, 2008 Response, and amended and prosecuted thereafter, embraced the elected "MSR-7" species. Dispositive of the issue is the Final Action, in which the Examiner explicitly acknowledged that the claims presented previously and then amended always read on the necessary MSR-7 sequences: "The examiner agrees that claim 1 and dependent claims still encompass the elected antibody of MSR-7." (Paper No. 20090422 at 3, emphasis added).

As the record reflects and as detailed below, the evident confusion arose because the sequence listing included multiple different SEQ ID Nos. for individual identical sequences, and the Examiners and Applicants unfortunately focused upon

different SEQ ID Nos. when it came to the issue of the elected MSR-7 species. When the record is studied, it will be appreciated (as the Examiners did during examination) that Applicants properly responded to the restriction requirement and that subsequent clarifying claim amendments were simply that, *i.e.*, for clarification, not for correcting an omission.

The alleged omission is that the claims failed to include the elected MSR-7 species.

The October 14, 2008 Office Action indicated that a reply has an omission which must be corrected, and thus appeared to be an Office Action issued under 37 CFR 1.135(c)(3). In this Office Action, the Examiner alleged that the **July 28, 2008 Supplemental Response** “canceling all claimed subject matter drawn to the elected invention and presenting only claims drawn to a non-elected invention is non-responsive.” (Paper No. 20081009 at 1).

The Examiner asserted that “[a]ccording to Applicants' specification (e.g. Figure 4 and sequence listing), the 6 CDR sequences for the elected MSR-7 antibody are L-CDR1=SEQ ID NO: 143, L-CDR2=SEQ ID NO: 144, L-CDR3=SEQ ID NO: 18, H-CDR1=SEQ ID NO: 146, H-CDR2=SEQ ID NO: 147 and H-CDR3=SEQ ID NO: 24.” (*Id.*) The Examiner concluded, “[t]hus, newly amended claim 1 and newly presented claim 41 (as of [the] amendment dated **02 July 2008**) and dependent claims are directed to an invention(s) that is independent or distinct from the invention originally claimed because none of the claims encompass the CDR sequences of the elected MSR-7 species.” (*Id.*, emphasis added) The Examiner further asserted “[s]ince the above-mentioned amendment appears to be a bona fide attempt to reply, applicant is

given a TIME PERIOD of ONE (1) MONTH or THIRTY (30) DAYS, whichever is longer, from the mailing date of this notice within which to supply the omission or correction in order to avoid abandonment.” (*Id.*)

Thus, in the October 14, 2008 Office Action, the Examiner alleged that the July 28, 2008 Supplemental Response is non-responsive in view of the restriction requirement and gave details as to the nature of the omission—that the 6 CDR sequences of the elected MSR-7 species were not included in the amended claims. We note, however, it was not clear whether the Examiner also alleged that the earlier July 2, 2008 Response was non-responsive for the same reason as well, because the July 2, 2008 Response was mentioned in the context of the allegation that “none of the claims encompass the CDR sequences of the elected MSR-7 species” (Paper No. 20081009 at 1).

As we will show below, neither response had an omission as alleged by the Examiner.

The July 2, 2008 Response did not have an omission.

It is respectfully submitted that the amended claims of the July 2, 2008 Response encompassed the elected species of MSR-7, and thus, it is not a reply having an omission.

Examination of the July 2, 2008 Response reveals that it was fully responsive, not nonresponsive, because the particular SEQ ID NOs for MSR-7 mentioned by the Examiner on page 1 of Paper No. 20081009 were recited in amended independent claim 1 of the July 2, 2008 Response, as highlighted in bold below:



Claim 1. An antibody molecule capable of specifically recognizing two regions of the  $\beta$ -A4 peptide/A $\beta$ 4, wherein the first region comprises the amino acid sequence AEF RHDSGY as shown in SEQ ID NO: 1 or a fragment thereof and wherein the second region comprises the amino acid sequence VHHQKL VFFAEDVG as shown in SEQ ID NO: 2 or a fragment thereof, wherein said antibody molecule comprises

(a) a variable  $V_L$ -Region comprising complementary determining regions, L-CDR1, L-CDR2, L-CDR3, wherein:

- (1) L-CDR1 comprises a sequence selected from the group consisting of SEQ ID NOs: 96, 130-133, 141-**143**, 160, 175-177, 180, 189, 190, 200, 201, 206-211, and 224;
- (2) L-CDR2 comprises a sequence selected from the group consisting of SEQ ID NOs: 97, **144**, 161, and 212; and
- (3) L-CDR3 comprises a sequence selected from the group consisting of SEQ ID NOs: 16, **18**, 20, 75, 77, 79, 81, 83, 85, 87, 95, 98, 102, 103-107, 145, 149-159; 162, 166, 178, 183, 202, 213, 217, 218, 220, 385, 387, 389, 391, 393, 395, 397, 399, 401, 403, 405, 407, 409, 411 and 413; and

(b) a variable  $V_H$ -Region comprising complementary determining regions, H-CDR1, H-CDR2, H-CDR3, wherein:

- (1) H-CDR1 comprises a sequence selected from the group consisting of SEQ ID NOs: 99, **146**, 163, 203, and 214;
- (2) H-CDR2 comprises a sequence selected from the group consisting of SEQ ID NOs: 100, 108-129, 134-140, **147**, 164, 167-174, 179, 181, 182, 184-188, 191-199, 204, 205, 215, 219, and 221-223; and
- (3) H-CDR3 comprises a sequence selected from the group consisting of SEQ ID NOs: 22, **24**, 26, 61, 63, 65, 67, 69, 71, 73, 93, 101, 148, 165, 216, 355, 357, 359, 361, 363, 365, 367, 369, 371, 373, 375, 377, 379, 381, and 383. (The July 2, 2008 Response at 10, emphasis added.)

Because many SEQ ID Nos. were recited in amended claim 1, Applicants were invited at the Examiner Interview of July 9, 2008 to **clarify** or to **explain** "how the newly submitted claim amendments read on the elected invention." (Paper No. 20080718 at 1). This invitation to clarify was memorialized in the July 28, 2008 Interview Summary, which states:

The examiners informed applicants' representative that it is unclear how the newly submitted claim amendments read on the elected invention. It was proposed that Applicants' representatives submit a subsequent response to address this issue. (Paper No. 20080718 at 1, emphasis added).

Thus, it is clear that the July 2, 2008 Response did not omit an elected species in response to the restriction requirement, and it is respectfully submitted that the July 2, 2008 Response should not be characterized as having an omission that falls under 37 CFR § 1.704(c)(7).

The July 28, 2008 Supplemental Response is a supplemental response expressly requested by the Examiners and does not contain an omission.

While the Examiner alleged in the October 14, 2008 Office Action that there is an omission in the July 28, 2008 Supplemental Response, it is respectfully submitted that the July 28, 2008 Supplemental Response did not contain such an omission. The omission alleged by the Examiner, as detailed above and as set forth by the Examiner in the October 14, 2008 Office Action, is that none of the claims contain the 6 CDR sequences for the elected species. (Paper No. 20081009 at 1).

As we explained in an Examiner Interview on December 3, 2008, however, and as memorialized in the January 16, 2009 response, amended claim 1 of the July 28, 2008 Supplemental Response recites the six CDR sequences of MSR-7 antibody. The confusion was due to the fact that the six SEQ ID NOs. recited in claim 1 for the six CDRs of MSR-7 were different from the SEQ ID NOs. noted by the Examiner, because the sequence listing included redundant SEQ ID NOs. for the same CDR sequences. In an effort to simplify the claim in response to the Examiners' invitation

during the July 9 interview, we deleted the redundant SEQ ID NOs., including, unfortunately, the particular SEQ ID NOs. recited by the Examiner in the October 14, 2008 Office Action. Still recited in the claim, however, as they had always been, were the sequences of the six CDRs of the elected MSR-7 species.

Indeed, in the Final Office Action attached hereto as Exhibit 7, the Examiner acknowledged that "Applicants' arguments have been fully considered and are found persuasive. The examiner agrees that claim 1 and dependent claims still encompass the elected antibody of MSR-7." (Paper No. 20090422 at 3, emphasis added). Therefore, it is respectfully submitted that the amended claims in the July 28, 2008 Response was responsive and that this Response did not contain an omission under 37 CFR § 1.704(c)(7), either.

Instead of characterizing the July 28, 2008 Supplemental Response as a reply having an omission, it is respectfully submitted that the July 28, 2008 Supplemental Response was a supplemental reply (1) expressly requested by the Examiner and (2) correcting an oversight or misunderstanding by the Examiner, an oversight ultimately acknowledged by the Examiner. See also the first paragraph on page 2 of the July 28, 2008 Supplemental Response: "During the interview, the Examiners noted the restriction requirement and the search requirements implicated by the previously amended claims and requested additional amendments and/or remarks to facilitate examination of the elected subject matter." Because the July 28, 2008 Supplemental Response was a supplemental response expressly requested by the Examiners, it falls within the exception set forth in 37 CFR § 1.702(c)(8) and therefore,

this is an additional reason that the period of time between its submission and that of the July 2, 2008 Response is not subject to reduction of the patent term adjustment.

### **Applicants' Patent Term Adjustment Calculation**

Based on the foregoing, applicants are entitled to a patent term adjustment of **291** days under 37 CFR §§ 1.703(a), 1.704(b), and 1.704(c)(8), because (1) neither the July 2, 2008 Response nor the July 28, 2008 Response contained an omission under 37 CFR § 1.704(c)(7), and (2) the PTO erred in calculating the patent term adjustment.

The requested adjustment of **291** days is calculated according to the formulas set forth in 37 CFR § 1.703 (a)(1) and §§ 1.704(b) and (c)(8):

Ground for Adjustment	Number of days	Explanation
§ 703(a)	394	May 8, 2006 (the day after the date that is fourteen months after the date the application fulfilled the requirements of 35 U.S.C. § 371) to June 5, 2007 (the date of mailing of the Restriction Requirement).
§ 704(c)(8)	10	July 28, 2007 (the day after the date that a response was received in the Office) to August 6, 2007 (the submission of the First Supplemental IDS)
§ 704(c)(8)	19	October 26, 2007 (the day after the date that a response was received in the Office) to November 13, 2007 (the submission of the Second Supplemental IDS)
§ 704(b)	65	April 29, 2008 (the day after the date that is three

Ground for Adjustment	Number of days	Explanation
		months after the January 28, 2008 Office Action was mailed) to July 2, 2008 (the date the Response was received in the Office)
§ 704(b)	2	January 15, 2009 (the day after the date that is three months after the October 14, 2008 Office Action was mailed) to January 16, 2009 (the date the Response was received in the Office)
§ 704(c)(8)	5	January 17, 2009 (the day after the date that a response was received in the Office) to January 21, 2009 (the submission of the Third Supplemental IDS)
§ 704(b)	2	July 30, 2009 (the day after the date that is three months after the April 29, 2009 Final Rejection was mailed) to July 31, 2009 (the date the Response to the Final Office Action was received in the Office)

As shown by our calculations, the term for the allowed patent should be **291** days (394-10-19-65-2-5-2=291), not just 95 days.

**Terminal Disclaimer**

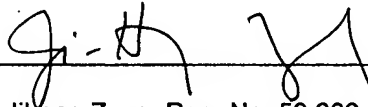
Upon information and belief, the undersigned represents that the patent to issue based on the above-identified application is not subject to a terminal disclaimer (37 CFR § 1.705 (b)(2)(iii)).

**Summary**

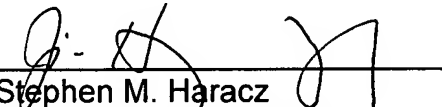
For the foregoing reasons, applicants respectfully request that **291** days be added to the term of the patent (instead of 95 days).

Please contact the undersigned if there are any questions regarding this paper.

I hereby certify that this correspondence (including the check and other papers identified as being enclosed) is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-14501, on October 14, 2009.

  
Jihong Zang, Reg. No. 56,606

Respectfully submitted,

By:   
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Select New Case	Application Data	Transaction History	Image File Wrapper	Patent Term Adjustments	Continuity Data	Foreign Priority	Published Documents	Address & Attorney/Agent	Supplemental Content
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## Patent Term Adjustment

Filing or 371(c) Date:	03-07-2005	USPTO Delay (PTO) Delay (days):	394
Issue Date of Patent:	-	Three Years:	-
Pre-Issue Petitions (days):	+0	Applicant Delay (APPL) Delay (days):	299
Post-Issue Petitions (days):	+0	Total Patent Term Adjustment (days):	95
USPTO Adjustment (days):	+0	<a href="#">Explanation Of Calculations</a>	

## Patent Term Adjustment History

Date	Contents Description	PTO(Days)	APPL(Days)
08-21-2009	Mail Notice of Allowance		
08-19-2009	Document Verification		
08-19-2009	Notice of Allowance Data Verification Completed		
08-19-2009	Case Docketed to Examiner in GAU		
08-14-2009	Examiner's Amendment Communication		
06-17-2009	Examiner Interview Summary Record (PTOL - 413)		
07-31-2009	Information Disclosure Statement considered		
07-31-2009	Information Disclosure Statement (IDS) Filed		
08-05-2009	Date Forwarded to Examiner		
07-31-2009	Amendment after Final Rejection		2
07-31-2009	Information Disclosure Statement (IDS) Filed		↑
04-29-2009	Mail Final Rejection (PTOL - 326)		↑
12-03-2008	Examiner Interview Summary Record (PTOL - 413)		
04-27-2009	Final Rejection		
01-21-2009	Information Disclosure Statement considered		
01-21-2009	Information Disclosure Statement (IDS) Filed		5
02-04-2009	Date Forwarded to Examiner		↑
01-16-2009	Response after Non-Final Action		198
01-16-2009	Request for Extension of Time - Granted		↑
01-21-2009	Information Disclosure Statement (IDS) Filed		↑
10-14-2008	Mail Notice of Informal or Non-Responsive Amendment		↑
08-12-2008	CRF Is Good Technically / Entered into Database		↑
08-08-2008	Date Forwarded to Examiner		↑
07-28-2008	Supplemental Response		↑
08-08-2008	Date Forwarded to Examiner		↑
07-02-2008	Informal or Non-Responsive Amendment after Examiner Action		↑
07-02-2008	Response after Non-Final Action		65
07-02-2008	Request for Extension of Time - Granted		↑
07-28-2008	Mail Examiner Interview Summary (PTOL - 413)		↑
07-28-2008	Mail Miscellaneous Communication to Applicant		↑
07-09-2008	Examiner Interview Summary Record (PTOL - 413)		↑
06-13-2008	Miscellaneous Communication to Applicant - No Action Count		↑
01-28-2008	Mail Non-Final Rejection		↑
01-22-2008	Non-Final Rejection		
11-13-2007	Information Disclosure Statement considered		
11-13-2007	Reference capture on IDS		
11-13-2007	Information Disclosure Statement (IDS) Filed		19
11-13-2007	Information Disclosure Statement (IDS) Filed		↑
11-07-2007	Date Forwarded to Examiner		↑
10-25-2007	Response after Non-Final Action		↑
10-18-2007	Mail Miscellaneous Communication to Applicant		

10-15-2007	Miscellaneous Action with SSP	
08-06-2007	Information Disclosure Statement considered	
10-10-2007	Case Docketed to Examiner in GAU	
08-06-2007	Reference capture on IDS	
08-06-2007	Information Disclosure Statement (IDS) Filed	10
08-06-2007	Information Disclosure Statement (IDS) Filed	↑
08-04-2007	Date Forwarded to Examiner	↑
07-27-2007	Response to Election / Restriction Filed	↑
07-27-2007	Request for Extension of Time - Granted	
06-05-2007	Mail Restriction Requirement	394
05-29-2007	Requirement for Restriction / Election	↑
12-14-2005	Case Docketed to Examiner in GAU	↑
09-20-2005	IFW TSS Processing by Tech Center Complete	↑
09-20-2005	Case Docketed to Examiner in GAU	↑
03-07-2005	Oath or Declaration Filed (Including Supplemental)	↑
04-11-2005	Cleared by OIPE CSR	↑
03-07-2005	371 Completion Date	↑
03-30-2005	Application Dispatched from OIPE	
03-30-2005	Notice of DO/EO Acceptance Mailed	
03-07-2005	Additional Application Filing Fees	
03-07-2005	A statement by one or more inventors satisfying the requirement under 35 USC 115, Oath of the Applic	

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